Remarks

I. Support for Amendments

Upon entry of the foregoing amendments, claims 1 and 8-13 are pending in the application. None of the seven original and previously-added claims are currently amended. Support for the previously-added claim amendments and previously-added claims may be found throughout the specification and in the original claims, for example at page 10, lines 1-7, at page 16, lines 20-25, at page 19, line 1 through page 20, line 12, and at page 25, line 21 through page 27, line 20. Upon entry of the foregoing amendments, claims 1 and 8-13 are pending in the application. No new matter enters by these amendments.

The specification has been amended to remove embedded hyperlinks and/or other forms of browser-executable code. No new matter enters by these amendments. The URL addresses themselves contained throughout the specification do not constitute browser-executable code in the absence of embedded hyperlinks and/or other forms of browser-executable code. The specification as amended does not contravene stated PTO policy of prohibiting live web links to other web pages, which might be commercial. (MPEP, § 608.01 (d).)

Applicants note the Examiner's comment regarding the use of the trademark "Microsoft." Applicants respectfully submit that "Microsoft" is capitalized as it appears on page 85, line 4, and that "Microsoft" is accompanied by the generic terminology "[t]he sequence information can be represented in a word processing text file, formatted in commercially-available software such as WordPerfect and Microsoft Word." Specification at page 85, lines 3-4. Applicants therefore respectfully submit that no amendment to the specification is required.

II. Response to Arguments

Applicants note that the Office has apparently not accepted Applicants' arguments, which the Office characterizes as "(1) the pending claim 1 is directed to a nucleic acid molecule which encodes a maize protein or fragment thereof comprising a nucleic acid sequence of SEQ ID NO: 1, (2) '974 Patent does not disclose SEQ ID NO: 1." Office Action at page 2. Applicants respectfully disagree. First, Applicants respectfully submit that claim 1 is directed to "[a] substantially purified nucleic acid molecule that encodes a maize protein or fragment thereof comprising a nucleic acid sequence of SEQ ID NO: 1." Second, Applicants respectfully note that it does not appear that the Office has presented any context in which the Office's characterization of Applicants' arguments would be understood. For example, the Office has not reiterated any rejections under 35 U.S.C. § 102(e) or 35 U.S.C. § 112, second paragraph (claim indefiniteness), which rejections were originally presented in the Office Action mailed August 16, 2002 (paper number 9), and to which Applicants responded with the above-referenced arguments. Applicants maintain their traversal of the rejections presented in the Office Action mailed August 16, 2002, and respectfully request clarification of the status of these rejections.

III. Rejections under 35 U.S.C. § 101

Claims 1 and 8-13 stand rejected under 35 U.S.C. § 101, first paragraph, as allegedly lacking a "specific and substantial" asserted utility or a well-established utility. Office Action at page 3. Specifically, the Office states that "[t]he specification asserts that the DNA SEQ ID NO: 1 can be utilized (1) to generate marker nucleic acids in order to detect polymorphism, and (2) to produce antibodies. Any DNA fragment can serve as a probe...[or] can be utilized to produce antibodies. For the reasons set forth above, the claimed invention is not supported by either a "specific and substantial" asserted utility of well-established utility." Office Action at page 3.

Applicants respectfully disagree. Applicants respectfully submit that the application of the Interim Guidelines ignores the presently disclosed utilities and contravenes well-established doctrines of utility developed in the courts. It is well-established law that "when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown." *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983). As acknowledged by the Examiner, the specification describes multiple objectives and utilities that are met by the present invention. For example, the claimed nucleic acid molecules are useful in determining the presence of polymorphisms, isolating specific promoter sequences, and to obtain nucleic acid homologues, *etc.* (*see, e.g.,* specification, beginning at page 34, under heading "Uses of the Agents of the Invention").

Many of these uses are directly analogous to the use of a microscope. An important utility of a microscope resides in its use to identify and characterize the structure of biological tissues in a sample, cell, or organism. Significantly, the utility of a microscope under 35 U.S.C. § 101 is not compromised by its use as a tool in this manner. Many of the presently disclosed utilities are directly analogous to the utilities of a microscope, *i.e.,* the claimed nucleic acid molecules may be used to identify and characterize nucleic acid molecules within a sample, cell, or organism. Such utility is indistinguishable from the legally sufficient utility of a microscope. Thus, the presently disclosed sequences possess the requisite utility under 35 U.S.C. § 101.

In the Office Action, the Examiner attempts to undermine the existing utilities by stating that they are generally applicable to "any DNA fragment," Office Action at page 3, and not particular or specific to the polynucleotide claimed. In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose. This position is wrong as a matter of law – there is no

requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renshaw PLC,* 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result...").

Such an argument implies that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.,* hitting golf balls. Such a result is not only untenable, but requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty,* 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933). Thus, it must be the case that a utility, generic to a broad class of molecules, does not compromise the specific utility of an individual member of that class.

Applicants note that the claimed nucleic acid molecules encompass many utilities. Some of these utilities may be common to a broader class of molecules. For instance, nucleic acid sequences may generally be used to identify and isolate related sequences. However, when used in this manner, the result is not generic. Rather, the claimed nucleic acid molecules will identify a ***unique*** subset of related sequences. This subset of related sequences is specific to the claimed sequence and cannot be identified by any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide this specific utility. Referring again to the golf club analogy, the club is still generically hitting a golf ball, but is uniquely designed to hit the ball in a manner that is distinct from other clubs. Once again, Applicants assert that the claimed nucleic acid molecules exhibit the requisite utility under 35 U.S.C. § 101.

The Examiner states that the credibility of the presently asserted utilities has not been assessed. Office Action at page 3. Credibility is precisely the issue that the courts have emphasized in evaluating the adequacy of an asserted utility. Utility is determined "by reference to, and a factual analysis of, the disclosure of the application." *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *quoting Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner

"has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* The Examiner "must do more than merely question operability – [she] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert,* 524 F.2d 1222, 1224-25, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 2107.01 ("Office personal are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided..."). Here, the Examiner has not even attempted to meet this burden. Thus, the Examiner's admission that the credibility of the disclosed utilities is not challenged is tantamount to an admission that no proper rejection has been made.

In view of the above, Applicants contend that the claimed nucleic acid molecules are supported by credible, specific, and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. An invention need only provide one identifiable benefit to satisfy 35 U.S.C. § 101. Because Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case, the rejection under 35 U.S.C. § 101 is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

IV. Rejections under 35 U.S.C. § 112, First Paragraph (Enablement)

Claims 1 and 8-13 stand rejected under 35 U.S.C. § 112, first paragraph, on the grounds that, as claims 1 and 8-13 allegedly lack a "specific and substantial" asserted utility or a well-established utility, one skilled in the art would therefore allegedly not know how to use the claimed invention so that it would operate as intended without undue experimentation. Office Action at page 4. Applicants respectfully traverse this rejection, and submit that this rejection has been overcome by the foregoing arguments

regarding utility. Applicants therefore respectfully request reconsideration and withdrawal of the enablement rejections under 35 U.S.C. § 112, first paragraph.

V. Rejections under 35 U.S.C. § 112, First Paragraph (Enablement)

Claims 1 and 8-13 also stand rejected under 35 U.S.C. § 112, first paragraph, on the grounds that "undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope." Office Action at page 5. The Office alleges that "[d]ue to the large quantity of experimentation necessary to generate the infinite number of derivatives recited in the claims and possibly screen same for activity, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure and function, and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope." Office Action at page 5. Applicants respectfully disagree.

Applicants respectfully bring to the Office's attention that claims 1 and 8-13 are not directed to polypeptide sequences, nor to "active muteins." Office Action at page 4, line 22. Claim 1, for example, is directed to *a substantially purified nucleic acid molecule* that encodes a maize protein or fragment thereof comprising a nucleic acid sequence of SEQ ID NO: 1. The Office seems to suggest that claims 1 and 8-13 are nevertheless limited in scope to "active muteins." Applicants respectfully submit that they know of no such legal requirement.

Applicants also submit that, even if claims 1 and 8-13 were in fact limited in scope to "active muteins," the specification disclosure is adequate to enable one of skill in the art to identify such "active muteins" without undue experimentation. For example, the specification describes the degeneracy of the genetic code (*see, e.g.,* specification at page 22, lines 16-23), conservative amino acid substitutions (*see, e.g., s*pecification at

page 22, line 24 through page 25, line 20), and the identification of single nucleotide polymorphisms (*see, e.g.,* specification at page 26, line 10 through page 27, line 20). It is well-established that patent applicants need not teach "conventional and well-known genetic engineering techniques," such as routine functional screening or nucleic acid sequencing of putative mutant clones. *See, e.g., Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000). Performing routine and well-known steps cannot create undue experimentation even if it is laborious. *See In re Wands*, 858 F.2d at 737, 8 U.S.P.Q.2d at 1404; *In re Angstadt*, 537 F.2d 498, 504, 190 U.S.P.Q. 214, 218-219 (C.C.P.A. 1976).

Finally, Applicants respectfully assert that the subject matter of claims 1 and 8-13 has been described in the specification in a manner adequate to enable one of skill in the art to make and use the claimed invention without undue experimentation. Applicants have described the complete chemical structure of SEQ ID NO: 1. For example, Applicants respectfully submit that, given the complete chemical structure of SEQ ID NO: 1, one of ordinary skill in the art would understand how to use the sequence of SEQ ID NO: 1 for the uses described in the specification, *e.g.,* identifying promoters and associated regulatory sequences (page 36, line 16 through page 38, line 6), and identifying polymorphisms (page 39, line 6, through page 46, line 3). As stated above, patent applicants need not teach "conventional and well-known genetic engineering techniques." *E.g., Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000). Patents "are written to enable those skilled in the art to practice the invention, not the public." *W.L. Gore & Assoc., Inc. v Garlock, Inc.,* 721 F.2d 1540, 1556, 220 U.S.P.Q. 303, 315 (Fed. Cir. 1983). Furthermore, the level of skill in this art is high, and the performance of routine and well-known steps cannot create undue experimentation even if it is laborious. *See In re Wands*, 858 F.2d at 737, 8 U.S.P.Q.2d at 1404; *In re Angstadt*, 537 F.2d 498, 504, 190 U.S.P.Q. 214, 218-219 (C.C.P.A. 1976).

Accordingly, for at least these reasons, Applicants therefore respectfully request reconsideration and withdrawal of the enablement rejections under 35 USC § 112, first paragraph.

VI. Rejections under 35 U.S.C. § 112, first paragraph (Written Description)

Claim 1 stands rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Office Action at page 5. Applicants disagree.

Applicants respectfully disagree with the Office's characterization of Claim 1 as "directed to a maize protein." Office Action at page 6. As stated above, Applicants respectfully submit that claim 1 is not directed to a polynucleotide sequence; rather, it is directed to a *substantially purified nucleic acid molecule* that encodes a maize protein or fragment thereof comprising a nucleic acid sequence of SEQ ID NO: 1.

The Office alleges that the breadth of enablement is not commensurate with the scope of the claim 1, and that "EST technology is highly unpredictable." Office Action at page 6. Applicants disagree, and respectfully submit that the Office has apparently merged the enablement and written description requirements. The enablement requirement of 35 U.S.C. 112, first paragraph is separate and distinct from the description requirement. *Vas-Cath, Inc. v. Mahurkar,* 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116-17 (Fed. Cir. 1991). Furthermore, Section 2163 of the MPEP states that a general allegation of unpredictability in the art is not a sufficient reason to support a rejection for lack of adequate written description. MPEP § 2163 at 2100-169. For at least these reasons, applicants respectfully submit that the rejection of claim 1 under 35 U.S.C.§ 112, first paragraph, is in error. Applicants respectfully request reconsideration and withdrawal of the written description rejection under 35 U.S.C. § 112, first paragraph.

Conclusion

In view of the above, the presently pending claims are believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass the application to issue. The Examiner is encouraged to contact the undersigned at (202) 942-5000 with respect to any unresolved issues remaining in this application.

Respectfully submitted,

Lawrence M. Lavin

Lawrence M. Lavin, Jr. (Reg. No. 30,768)
by Holly Logue Prutz (Reg. No. 47,755)
David R. Marsh (Reg. No. 41,408)

by Holly L Prutz

Date: July 9, 2003

MONSANTO COMPANY
800 N. Lindbergh Blvd.
Mailzone N2NB
St. Louis, MO 63167
(314) 694-3602 telephone
(314) 694-1671 facsimile